

Pharma Export Procedure and Documentation

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Venue : EXIM Bank, Ahmedabad

PRESENTATION

By

DR.P.V.APPAJI

M.Pharm, Ph.D

EXECUTIVE DIRECTOR

PHARMEXCIL

(PHARMACEUTICALS EXPORT PROMOTION COUNCIL)

Set up by Ministry of Commerce and Industry

GOVERNMENT OF INDIA

What is Export - Why Exports

- *Export is selling a Product Outside the National Market*
- *Export is to utilize opportunity in the Overseas Market*
- *It can be an Exclusive activity or additional to domestic activity*
- *Earlier companies preferred it for utilizing spare capacities*
- *Products are sold at nominal margins*
- *To earn foreign exchange*

What we should look for entering into Exports

- a. Overseas Demand*
- b. Price*
- c. Local Competition*
- d. Local Government Policy*
- e. Market Environment*
- f. Distribution Channels*
- g. Product Standards/ Quality*

What are the Requirements

- a. Adequate Finance*
- b. Good Manufacturing Facilities*
- c. Good Communication System*
- d. Knowledge on International Trade/ Procedures*
- e. Quality Consciousness*

How to get Information

- a. Marine Products Export Development Authority (MPEDA)*
- b. Associates/ Acquaintances*
- c. Yellow Pages*
- d. Trade Delegations*
- e. Exhibitions and Trade Fairs*

Normal Causes of Failure

- a. Lack of Understanding of the Market
Environ*
- b. Poor Finance Planning*
- c. Failure to meet the Overseas Health
Specifications, Packaging Stipulations,
Labeling Needs, Standards etc.*
- d. Failure to Adhere to the Committed Delivery
Schedules*

General Steps Involved

- a. Decide to enter the Overseas Market*
- b. Form the Market Research Department*
- c. Arrange for Bank Credit Limits*
- d. Obtain PAN from the Income Tax Dept.*
- e. Obtain the Importer-Exporter Code number from the JDGFT*
- f. Registration with EPC*
- g. Identify Local Agent / Consultant*

Contd..

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General Steps Involved

- h. Submit Documents for Registration*
- i. Quote Price/ Negotiate Price & Terms*
- j. Get Order*
- k. Arrange for Pre-shipment Credits from ECGC/
Bank*
- l. Nominate service agencies for Customs &
Logistics*
- m. Register the export order with the Authorised
Agencies, if exports attract any incentives*

Some Related Important Government Laws

- a. *Foreign Trade (Development & Regulation) Act 1992*
- b. *Foreign Exchange Management Act & RBI Regulations*
- c. *Customs Act 1962*
- d. *Customs Tariff Act*
- e. *Central Excise Act 1994 & Rules*
- f. *Sales Tax Acts*
- g. *Drugs & Cosmetics Act*
- h. *Narcotics Regulations etc.*

Foreign Trade Policy

- a. Notified under Section 5 of Foreign Trade Act 1992*
- b. Period of operation is 5 years (Apr 2004 to Mar 2009)*

Some Important Definitions

- *Exporter – A person who Exports or intends to Export and holds an I.E.Code*
- *Manufacture Exporter – A person who manufactured goods by himself*
- *Merchant Exporter – A trader engaged in Exporting activities*
- *Status Holder – Exporter recognized as Export House/ Trading House by DGFT*
- *Third Party Exports – Exports made by an Exporter on behalf of another Exporter (Shipping bill to indicate both)*

Some Commonly used Abbreviations

- *ALC – Advance Licensing Committee in DGFT*
- *DEPB – Duty Entitlement Pass Book*
- *DFRC – Duty Free Replenishment Certificate*
- *DTA – Domestic Tariff Area*
- *EOU – Export Oriented Unit*

Contd..

Some Commonly used Abbreviations

- *ITC – Indian Trade Classification*
- *RCMC – Registration Cum Membership Certificate*
- *SEZ – Special Economic Zone*
- *SION – Standard Input Output Norms*
- *Drawback – Rebate of duty chargeable on Imported materials used in Exported goods*

Types of Exports

- *Commodity Exports*
- *Service Exports*
- *Deemed Exports*

Transactions in which the goods supplied do not leave the country but consumed in an Exported Material

Documentation

- *Certificate of Origin (Preferential / Non Preferential)*
- *Shipping Bills*
 - *Duty Free Shipping Bill*
 - *Drawback Shipping Bill*
 - *Ex-Bond Shipping Bill*
 - *Dutiable Shipping Bill*
 - *DEPB Shipping Bill*

Documents with Shipping Bill

- *Supplier's Order Copy*
- *Letter of Credit Copy*
- *Commercial Invoice – 6 Copies*
- *Packing List – 6 Copies*
- *G.R. Form/ P.P. Form – Original & Duplicate*
- *Customs Declaration*

Contract of Sale

- *General Terms of sales covered by sale of goods act 1924*
- *Ex-Works*
- *FOB (Free on Board)*
- *C & F (Cost & Freight)*
- *CI F (Cost Insurance & Freight)*

Status Holders

Category

Performance

One Star Export House

Rs. 15.00 crores

Two Star Export House

Rs. 100.00 crores

Three Star Export House

Rs. 500.00 crores

Four Star Export House

Rs. 1500.00 crores

Five Star Export House

Rs. 5000.00 crores

Privileges for Status Holders

- *Custom clearances on self declaration basis*
- *Input / Output norms in 60 days*
- *Exemption from compulsory negotiation through bank*
- *100% retention of FE received*
- *FE realisation in 360 days*
- *Entitlement under Target Plus Scheme*

Useful Websites

- www.busyindia.com
- www.alibaba.com
- www.tradeport.com
- www.trade-india.com/bbsnew/
- www.markettradefair.com
- www.eximkey.com

Global Pharma Exports

Year	Value US \$ Billions	% Growth
2000	106.34	2.68
2001	131.74	23.89
2002	164.08	24.54
2003	199.41	21.53
2004	243.71 (Rs.1100 thousand Crs)	22.22

Total Countries (142)

2004 India's Contribution 2.29 (0.94% Share)

Source Data : Intracen

Export Performance

- **2001-02: Rs. 9856.29 Crs.**
- **2002-03: Rs. 12826.10 Crs.**
- **2003-04: Rs. 15213.24 Crs.**
- **2004-05: Rs. 17857.80 Crs.**
- **2005-06: Rs. 21578.96 Crs.**

**Ranks 4th in Exports “Principal Commodity” wise with
4.74% Contribution**

Top Global Pharmaceutical Exporting Countries

Year 2004

<i>S.No</i>	<i>Country</i>	<i>Value US \$ Billions</i>
<i>1</i>	<i>Germany</i>	<i>34.03</i>
<i>2</i>	<i>Belgium</i>	<i>30.77</i>
<i>3</i>	<i>USA</i>	<i>23.34</i>
<i>4</i>	<i>Switzerland</i>	<i>23.03</i>
<i>5</i>	<i>UK</i>	<i>22.43</i>
<i>..15</i>	<i>China</i>	<i>3.23</i>
<i>..17</i>	<i>India</i>	<i>2.29</i>
<i>..56</i>	<i>Pakistan</i>	<i>0.06</i>

Indian Pharmaceutical Industry – Key Strengths

- *Strong manufacturing base*
- *Cost competitiveness*
- *Network of laboratories and R& D infrastructure*
- *Highly trained pool of scientists and professionals*
- *World-class quality products*
- *Strong marketing and distribution network*
- *Strong process development skills*
- *Potential ground for clinical trials*
- *Fast growing health care industry*
- *Rich biodiversity*
- *Growing biotechnology industry*

Approvals Received from Some Developed Countries

COMPANIES / FACILITIES

FDA - UNITED STATES 100

TGA - AUSTRALIA 19

MCA- SOUTH AFRICA 45

EDQM - EUROPE 13

Export of Pharmaceuticals

<i>Year</i>	<i>Bulk Drugs</i>	<i>Formulations</i>
<i>2002-03</i>	<i>Rs. 5726.01 cr</i>	<i>Rs. 6867.00 cr</i>
<i>2003-04</i>	<i>Rs. 7178.45 cr</i>	<i>Rs. 7969.32 cr</i>
<i>2004-05</i>	<i>Rs. 8069.28 cr</i>	<i>Rs. 9732.34 cr</i>
<i>2005-06</i>	<i>Rs. 10692.16 cr</i>	<i>Rs. 10861.92 cr</i>

1. Requirements for Drug Manufactures

- *Entry to Regulated / Less Regulated / Non Regulated Markets*
- *Product range like Drugs / Intermediates / Bulk Drugs / Formulations / Nutraceuticals / Dietary Supplements*
- *Manufacturing Facility – WHO GMP preferred*

Contd..

2. Requirements for Drug Manufactures

- *Expertise in Documentation*
- *Understanding of Product Registration Requirements*
- *R & D support for Quality / Product Improvements*
- *Strict Delivery Schedule*
- *Idea on Patents*

Contd..

3. Requirements for Drug Manufactures

- *Effective Communication System (Internet / email)*
- *Executive from Foreign Trade background*
- *Ability to tour Foreign Countries*
- *Participation in Trade Fairs/ Exhibitions Abroad*

Registration Procedures

- *Almost all Countries require prior registration of products*
- *Source of getting registration formalities, forms etc.*
- *Preparation of dossiers for submission to the regulatory affairs*
- *Payment of Registration Fees – Receipt of payment*
- *Obtaining registration certificate from the regulatory authorities*

Pharma Export of Major Segments

<i>Bulk Drugs</i>	<i>35.9%</i>
<i>Formulations</i>	<i>34.5%</i>
<i>RM / C / Intmed.</i>	<i>26.2%</i>
<i>Biotech & Biopharma</i>	<i>1.8%</i>
<i>Medical Devices</i>	<i>1.2%</i>
<i>Ayurvedic & Herbal</i>	<i>0.4%</i>

Total Rs. 290 Billions

Top 10 Pharma Export Destinations

S.No. / Ranks	Countries	APR-2005-MAR-2006 Rs. Crs.
1	U S A	3062.24
2	GERMANY	1062.97
3	RUSSIA	1051.12
4	U K	820.63
5	CHINA P RP	762.55
6	BRAZIL	615.21
7	NIGERIA	512.17
8	CANADA	497.27
9	SOUTH AFRICA	442.18
10	TURKEY	426.22
224	GRAND TOTAL	21578.96

Fast Growing Export Markets

AMONG TOP 30 COUNTRIES / 71.38% CONTRIBUTION

2005-2006

COUNTRY	EXPORT VALUE	GROWTH%
	Rs. Cr.	
South Africa	442.18	104.13%
Israel	310.33	84.15%
Turkey	426.22	78.47%
Kenya	227.74	78.32%
Singapore	378.50	58.51%
United Kingdom	820.63	39.99%
China P RP	762.55	39.96%
Russia	1051.12	35.84%
Italy	411.98	35.38%
Vietnam Soc Rep	400.69	31.30%

Some Major Bulk Drugs (its Derivatives) Exported

2004-2005

<i>Bulk Drug</i>	<i>Rs. Cr.</i>
<i>Cefadroxil</i>	207.91
<i>Menthol</i>	187.50
<i>Amoxicilline</i>	126.84
<i>Erthromycin</i>	118.88
<i>Cephalexin</i>	99.49
<i>Sulphame Thoxazole</i>	63.99
<i>Ranitidine</i>	56.19
<i>Ampicilline</i>	55.26
<i>Ibuprofen</i>	48.40
<i>Ciprofloxacin</i>	41.03

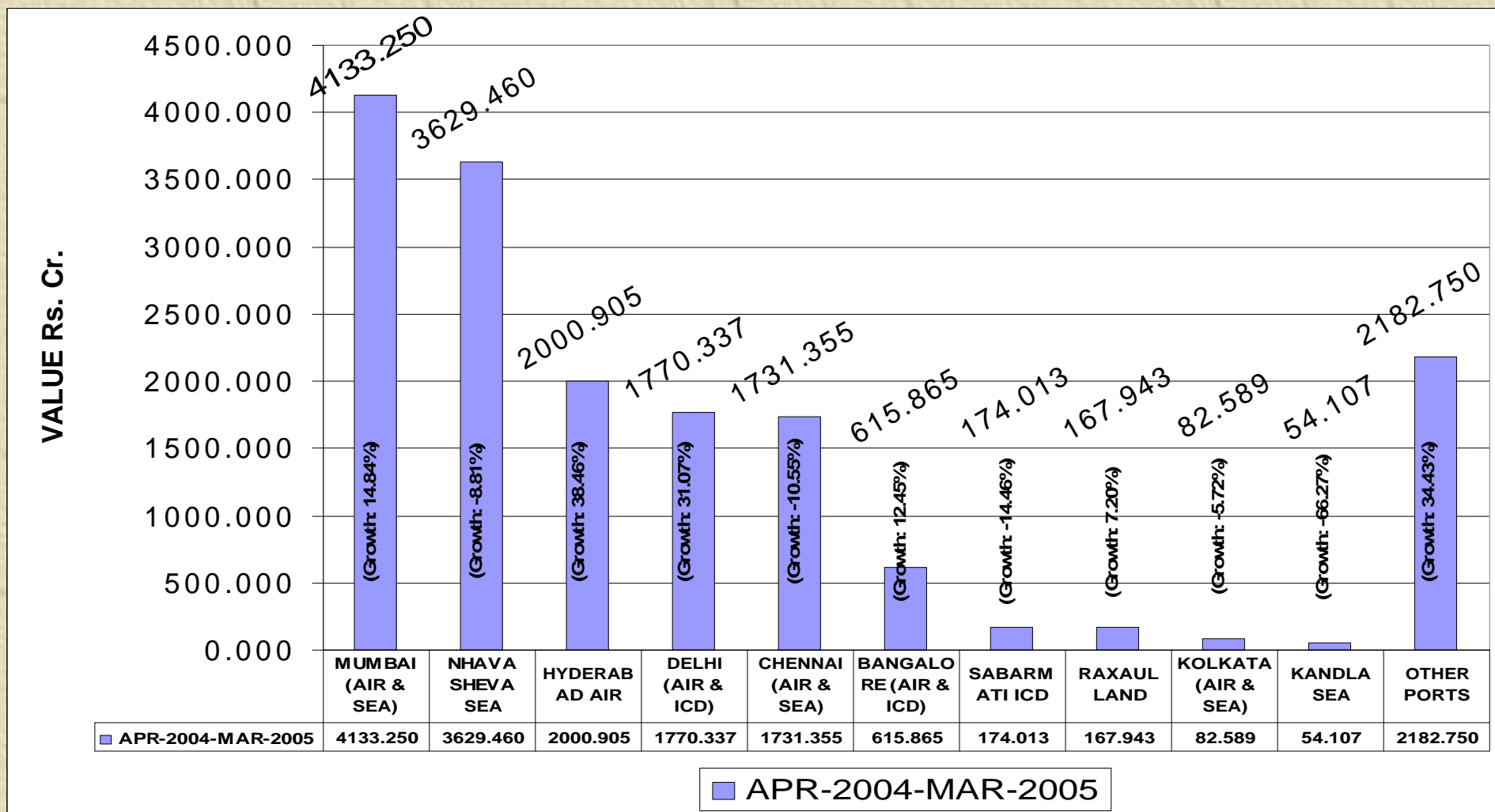
Some Major Formulations Exported

2004-2005

<i>Formulations</i>	<i>Rs. Cr.</i>
<i>Anti Biotics – Others</i>	<i>377.05</i>
<i>Ayurvedic Medicants</i>	<i>255.75</i>
<i>Amoxycillin in Capsules etc.</i>	<i>154.85</i>
<i>Ibuprofen Paracetamol & Combinations</i>	<i>141.35</i>
<i>Omeprazole & Lansoprazole</i>	<i>120.60</i>
<i>Insulin Injection</i>	<i>89.42</i>
<i>Tranquilizers</i>	<i>82.18</i>
<i>Mixed Vaccines for MMR</i>	<i>75.85</i>
<i>Cimetidine, Rantidine</i>	<i>73.17</i>
<i>Ciprofloxacin</i>	<i>69.17</i>

India's Export of Drugs, Pharmaceuticals & Fine Chemicals Through Major Ports

Above Rs. 50 Crs.



Some Major Pharma Exporters

March 2006

	Value Rs. Crs.
<i>Ranbaxy</i>	2337
<i>Cipla</i>	1514
<i>Dr.Reddys</i>	1197
<i>Aurobindo</i>	555
<i>Lupin</i>	761
<i>Orchid</i>	621
<i>Ipca</i>	386
<i>Biocon</i>	358

Normal Interactive Government Agencies

- *DGFT*
- *State/ Central Drug Control*
- *Excise*
- *Customs*
- *Pharmexcil*
- *Embassies*

Pharmexcil

Pharmaceuticals Export Promotion Council

- 1. Set up by Ministry of Commerce on 12 May, 2004*
- 2. Objective : To give Focused Attention to Pharma Exports*
- 3. Supported by : All Major Pharma Associations I DMA, BDMA, OPPI, IPA, ETC and Govt., of A.P.*
- 4. Rs. 3 Crores Contribution by Government of Andhra Pradesh*
- 5. H.O. at Hyderabad, R.O. at Mumbai & New Delhi*

Export Promotion Councils & their Role

- *Autonomous in Nature*
- *Government nominees on the Board*
- *Provide commercially useful information & Assistance*
- *Professional advise in technology related matters*

Contd..

Export Promotion Councils & their Role

- *Organize visits of Delegations to Explore Overseas Markets*
- *Participation in Trade Fairs/ Exhibitions*
- *Take up problems of members with the Government Agencies*
- *Build a statistical base & provide data on Exports*
- *Issue of RQMC's*

Pharmexcil - Categories Covered

- *Bulk drugs / drug intermediates*
- *Drug formulations*
- *Herbals / Ayurvedics / Homeopathic / Unani*
- *Medicinal Plants*
- *Bio-tech / Biological products*
- *Diagnostics and Surgicals*
- *Neutraceuticals*
- *Collaborative /contract research*
- *Clinical trials*
- *Pharma consultancy services etc.*

Authorized Agency for Pharmaceuticals

- *Foreign Trade Policy - August 2004*
- *Pharmaceutical items shifted from purview of Chemexil to Pharmexil.*
- *Focus areas: Focus CIS*
 - Focus Africa*
 - Focus Asean +2*
 - Focus LAC*

Assistance to Exporters

- *Issue of RCMC certificates*
- *Delegations to foreign countries*
- *Buyer seller meetings*
- *Foreign buyer details*
- *Embassy assistance*
- *Exhibition participation*
- *Seminars and Conferences*
- *Technology assistance*

Our Website - www.pharmexcil.com

Welcome To Pharmexcil - Microsoft Internet Explorer

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Back Forward Stop Home Search Favorites Refresh Print Mail Stop

Address <http://www.pharmexcil.com/v1/asp/Default.aspx>

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Council Updates

- ▶ Our Services
- ▶ Our Members with Websites
- ▶ Pharmexcil News 12/06*
- ▶ Trade Enquiries 15/06*
- ▶ Trade Statistics
- ▶ Country Reports/Publications (Council)
- ▶ Pharmexcil Calendar 17/05*
- ▶ Pharma Events 21/05*
- ▶ General Information 15/06*
- ▶ Pharma in Media 15/06
- ▶ Press Releases
- ▶ List of Latest Updates
- ▶ Committee of Administration

Welcome to Pharmexcil
A Council set up by Ministry of Commerce & Industry

- ▶ International Viewers LU 25/02*
- ▶ Country Wise LU 13/06*
- ▶ Product Category Wise LU 23/05*
- ▶ Conferences/ Presentations LU 07/06*

NEW

India - LAC International Pharma Meet
27th to 29th June 2007, HYDERABAD

[Click Here for More Details](#)

CPhI 2007 India **CPhI World Wide**

Register your Pharma Products Overseas and get 50% Reimbursement upto 50 Lakhs / annum as per Guidelines

Participate in Pharmexcil Organized Delegations / Exhibitions and get Airfare and / or Rs.80,000/-

Done

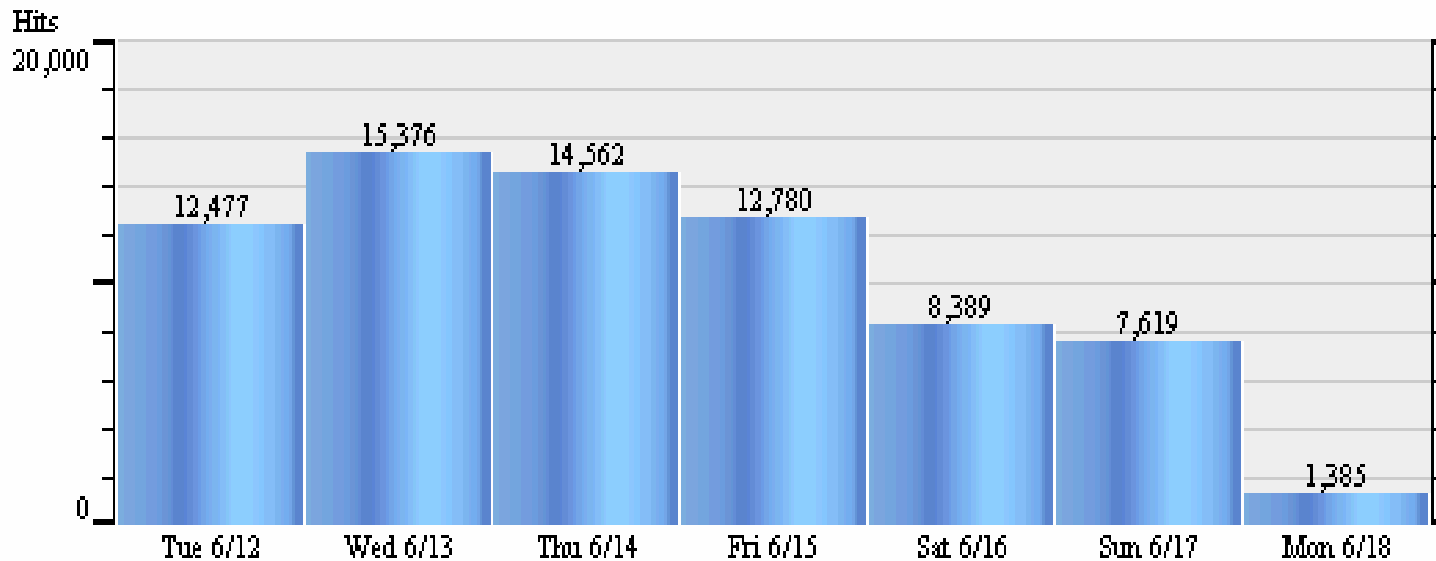
start Welcome To Pharmexcil...

Daily Hits on Website

Report: Hits Graph - phar11

Date Range: 06/12/2007 - 06/18/2007

Range Total: 72,588 Daily Average: 10,369.71



Daily Average : 10369

Daily Hits on Website

Report: Domain Drilldown - phar11
 Date Range: 06/12/2007 - 06/18/2007

Previous Filter #Shown 10 Go To# 1 Show/Hide

Domains (1-10) / 68	Sessions	Percent		
▶ com	2,017	28.91%		
▶ in	1,931	27.68%		
▶ (no entry)	1,763	25.27%		
▶ net	840	12.04%		
▶ edu	40	0.57%		
▶ uk	28	0.40%		
▶ de	27	0.39%		
▶ cn	24	0.34%		
▶ ru	23	0.33%		
▶ pk	20	0.29%		
View Total:	6,713	96.23%		
Total:	6,976	100.00%		

Government Incentives

Example of Public + Private Partnership

- 1. Reimbursement of AirFare in Foreign Delegation*
- 2. Support for participation in Foreign Exhibitions*
- 3. Part Reimbursement of Product Registration Charges*
- 4. Market Survey Reports*
- 5. National / International Conferences etc.*
- 6. Warehouse facilities in Foreign Countries*

Pharmexcil Calendar

Delegations

2007-2008

- 1. Delegation to Australia, New Zealand, Fiji*
- 2. Delegation to Tanzania, Congo, Uganda*
- 3. Delegation to Brazil, Venezuela, Mexico, Argentina*

Pharmexcil Calendar

Exhibitions

2007-2008

- 1. ILMAC, Switzerland*
- 2. CPHI World Wide 2007, Milan, Italy*
- 3. Xpo Pharm, Seoul, South Korea*
- 4. Pharmatech 2007, Russia & Ukraine*
- 5. API China 2007*
- 6. Asia Pharma Expo 2007*

Pharma Market - Country Reports

- *Tanzania*
- *EU Generics Market*
- *German Generics Market*
- *France Pharma Market*
- *Spanish Generics Market*

Further details browse www.pharmexcil.com

Requirements for Membership

- 1. Import Export Code Number*
- 2. SSI Certificate*
- 3. Bankers Certificate*
- 4. Drug License*
- 5. Fees (Rs.3000 / Rs. 4500 / Rs. 15000)*
- 6. For details visit our Website www.pharmexcil.com*

For Pharma Exports

Pharmexcil is

*The Gateway to Global
Pharma Trade*

MARKET ACCESS INITIATIVE
(MAI Scheme)

Revised as on 4th January 2007

ABOUT THE SCHEME:

Envisaged to act as a catalyst to promote India's export on a sustained basis.

OBJECTIVE:

Focus product-focus country approach to evolve specific market and specific product through market studies/survey.

Assistance would be provided to Export Promotion Organizations/ Trade Promotion Organizations/ National Level Institutions/ Research Institutions/ Universities/ Laboratories, Exporters, etc.,

For enhancement of export through accessing new markets or through increasing the share in the existing markets.

Marketing Projects Abroad

- *Opening of Showrooms & Warehouses;*
- *Organizing “Trade Festival of India*
- *National Level Participation in Major International Trade Fairs etc.;*
- *Display in International departmental stores;*
- *Publication of World Class Catalogues;*
- *Publicity Campaign and Brand Promotion;*
- *Research and Product Development;*
- *To support Recognized associations in Industrial clusters for marketing abroad;*
- *Reverse visits of the prominent buyers, etc., from the project focus countries.*

FINANCIAL ASSISTANCE UNDER THE SCHEME

✦ ACTIVITIES

✦ Marketing Projects Abroad

✦ Capacity Building

✦ Support for Statutory Compliances

✦ Studies

✦ Project Development

✦ Miscellaneous

Capacity Building

- *For imparting training to the Indian Exporters w.r.t. to export in general and on specific region/country basis;*
- *For up-gradation/improvements in Laboratories, Universities, Research Institutions on stand alone or Public Private Partnership basis for fulfilling SPS measures/related testing etc. including reimbursement of testing charges*
- *For quality up-gradation of select products for export markets (by skill upgradation using experts/designers, production process improvements, reduction in rejections etc.)*
- *For developing Common facility centers; design centers; packaging, etc.*

Support for Statutory Compliances

- *Charges/expenses for compliance of statutory requirements in the buyer country including Testing charges for engineering products abroad; Registration charges for product registration abroad for pharmaceuticals, bio-technology and agro-chemicals clinical trials for drugs/pharmaceuticals & medical disposables, medical equipment etc.*
- *Other commodities/product groups and the nature of compliance covered for reimbursement under the scheme shall be as approved by the Empowered Committee on a case to case basis.*
- *For contesting litigation(s) in the foreign country concerning restrictions/anti dumping duties etc. on particular product(s) of Indian origin. The commodity/ product groups, nature of litigation to be supported and the extent of support shall be as decided by the Empowered Committee on a case to case basis.*

Studies

- *Market studies/survey for evolving proper marketing strategies;*
- *Export Potential Survey of the States;*
- *Projects/Study which further the objectives of the schemes;*
- *WTO studies for evolving WTO compatible strategy;*
- *All Trade related studies including Joint Study Group(JSG), Free Trade Agreement(FTA), Regional Trade Agreement(RTA) studies etc. Only specific markets studies would be undertaken and these studies would be entrusted to reputed professional organizations.*

Eligible Agencies

- *Departments of Central Government and Organisation of Central/ State Governments including Indian Missions abroad*
- *Export Promotion Councils*
- *Registered Trade Promotion Organisation*
- *Commodity Boards*
- *Apex Trade Bodies recognized under Foreign Trade Policy of Government of India*
- *Recognised Industrial & Artisan Clusters*
- *Individual Exporters (only for statutory compliance etc.)*



Thanks You